Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

Protocol summary

Study aim

Determining the effect of olfactory training on improving the sense of smell in patients with covid 19 with olfactory disorders

Design

A clinical trial with a control group, with parallel groups, using a simple randomization method with closed envelopes, consisting of 50 patients in the intervention group and 50 patients in the control group. There is no blinding.

Settings and conduct

100 patients who have reported a disorder in the sense of smell are divided into groups by a simple random method. Both groups complete the olfactory disorders questionnaire. Then the intervention group is subjected to olfactory training with four scents of rose, eucalyptus, clove, and lemon. Olfactory training is a method in which patients perform olfactory training for 6 weeks twice a day, morning and night, each scent for 20 seconds with a 10 second interval between each scent. The control group does not perform olfactory training during this period. After 6 weeks, both groups complete the olfactory disorders questionnaire again.

Participants/Inclusion and exclusion criteria

The conditions for patients to enter the study are over 18 years of age and a laboratory finding of covid 19 infection, who mention olfactory disorders and do not have a history of other diseases affecting the olfactory system, as well as the use of corticosteroids.

Intervention groups

The intervention and control groups both complete the questionnaire. Then the patients of the intervention group undergo olfactory training for 6 weeks. The control group does not receive olfactory training during this period. Then both groups are re examined by the questionnaire and the results are compared with each other.

Main outcome variables

Severity of olfactory disorder in patients with covid 19, The effect of olfactory disorder on quality of life, The effect of olfactory training on olfactory disorders caused by covid 19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055612N1**
Registration date: **2023-01-27, 1401/11/07**
Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**
Update count: **0**

Registration date

2023-01-27, 1401/11/07

Registrant information

Name

Mohammad hossein Akbarpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3528 1966

Email address

mh.akbarpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-03-16, 1401/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

Public title

Evaluation of the Effect of Olfactory Training on Improving the Sense of Smell of COVID 19 Patients with Olfactory Dysfunction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult male and female (over 18 years old) who doesn't have a history of Olfactory Dysfunction before infection with Covid-19, a history of polyps in the nasal cavity, dependence on long term corticosteroids treatments for diseases such as Asthma and Chronic Obstructive Pulmonary Disease, a history of cerebrospinal fluid leakage, a history of Allergy to do not have Budesonide or other topical steroids Positive laboratory finding of Covid 19 Subjective complaint of loss of smell after infection The ability to read, write

Exclusion criteria:

patients with a history of Olfactory Dysfunction before infection with Covid 19, a history of polyps in the nasal cavity, dependence on long term corticosteroids treatments for diseases such as Asthma and Chronic Obstructive Pulmonary Disease, a history of cerebrospinal fluid leakage

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization, randomization unit: individual, randomization tool: Excel software, how to create a random sequence: using Excel's Rand function, concealment: in order to hide the random allocation using the method of sealed non-transparent envelopes Randomized sequence waxing (SNOSE) will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Pharmacy and Nursing and Midwifery school of Shahid Beheshti University of Medic

Street address

Niayesh intersection, Valiasr st.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.059

Health conditions studied

1

Description of health condition studied

کووید 19

ICD-10 code

U07.1

ICD-10 code description

U07.1: COVID-19, Virus identified

Primary outcomes

1

Description

Score by Questionnaire of Olfactory Disorders - Negative Statements

Timepoint

Beginning and six weeks after

Method of measurement

Questionnaire of Olfactory Disorders - Negative Statements

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who suffer from olfactory disorders Perform olfactory training, twice a day, in the morning and at night for 6 weeks, rotating for 20

seconds each with a ten-second interval between each scent, four scents of rose, eucalyptus, and cloves. and lemon.

Category
Treatment - Other

2

Description
Control group: Patients with covid-19 and olfactory disorders do not receive any treatment.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health deputy of Babol University of medical sciences

Full name of responsible person
Dr Mitra Zandi

Street address
Modarres

City
Babol

Province
Mazandaran

Postal code
1111111111

Phone
+98 11 1111 1111

Email
mh.akbarpour1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Ali Ziai

Street address
Shahid Chamran Highway, Evin

City
Tehran

Province
Tehran

Postal code
193954719

Phone
+98 21 2243 9951

Email
mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Hossein Akbarpour

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Pasdaran 10 st.

City
Babolsar

Province
Mazandaran

Postal code
4741858315

Phone
+98 11 3528 1966

Email
mh.akbarpour1@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Hossein Akbarpour

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Pasdaran 10

City
Babolsar

Province
Mazandaran

Postal code
4741858315

Phone
+98 11 3528 1966
Email
mh.akbarpour1@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Hossein Akbarpour
Position
Msc student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Pasdaran 10
City
Babolsar
Province
Mazandaran
Postal code
4741858315
Phone
+98 11 3528 1966
Email
mh.akbarpour1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data on main outcomes can be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
assessment of the effectiveness of the trainings 6 months after the study
From where data/document is obtainable
through the email address mh.akbarpour1@gmail.com
What processes are involved for a request to access data/document
the answer will be given one week after the requester sends an email to the mentioned email address.
Comments